

The rectal dilator was alleged to be misbranded in that representations in the labeling that it was a simple, harmless, convenient, nonhabit-forming, and ideal treatment to bring satisfactory results and permanently overcome constipation and piles by inducing natural and regular bowel movement by reaching and correcting the cause of constipation by strengthening and toning the muscles controlling defecation; that it would improve and strengthen the body, not weaken or injure it; that it would be efficacious in the treatment of piles and troubles caused by faulty elimination; that it would restore the sphincter muscles to a normal condition, relieve congestion of blood and establish a healthy, vigorous circulation; would relieve constipation of long standing; would bring health and comfort and promote more refreshing sleep, and would be efficacious to aid nature in conditions commonly associated with constipation such as coated tongue, foul breath, bad taste in the mouth, sallow skin, acne, erythema, urticaria, anemia, lassitude, mental hebetude, insomnia, more or less marked degree of anorexia, headache, "spurious" diarrhea, colicky pains caused by enterospasm, neuralgic pains, hemorrhoids, fissure pruritus, occasional prolapse, auto-intoxication, flatulence, indigestion, nervousness, irritability, and cold extremities; that recovery would be permanent and that one need have no fear of using it too long or too much, were false and misleading, since the article would not be efficacious for such purposes and might be used too long or too much.

The dilator was alleged to be misbranded further in that it would be dangerous to health when used with the frequency and duration prescribed, recommended, or suggested in the following labeling: (Carton) "Adults begin with No. 1 Dilator. First warm dilator in warm water; then lubricate outside of dilator with Dr. Young's Piloment (or if it is not available, with vaseline) and while in a squatting position—or while lying on the side with knees drawn up—gently insert in the rectum as far as the flange or rim. Hold in place a minute and the anal muscles will close and retain it. Sit or lie down and allow it to remain for half an hour or an hour to get the best results. Ten minutes will accomplish much. When ready to go to the next larger size, it is best first to use for a few minutes the same size you have been using, inserting and withdrawing it several times. This is very beneficial and should not be overlooked. Children. The Dilators should not be used by any child under 8 years except under the instructions of a physician. An 8 to 12 year old child may use progressively our Nos. 0, 1 and 1½ Dilators. \* \* \* Directions for use are the same as in the above paragraph for adults. Any larger sizes than these for children of these ages should be used only under direction of a physician. Children from 12 to 18 years should follow the same directions as those given for children from 8 to 12 years except that they may use the Nos. 2 and 2½ Dilators after they have used the smaller sizes according to directions. Try to use the Dilators each day; \* \* \* Keep your Dilators and make occasional use of them. \* \* \* Important: Do not neglect to use your Dilators; \* \* \* It is advisable to use occasionally as a precautionary measure. You need have no fear of using them too much."

Dr. Young's Piloment was alleged to be misbranded in that representations in the labeling that it would promote healing of piles, and that in conjunction with Dr. Young's Dilators it would be efficacious in the treatment of rectal irritation, and would be efficacious as an auxiliary treatment and relief of constipation and piles, was a soothing treatment for itching and bleeding piles, and would help in a more speedy recovery from piles, were false and misleading since it would not be efficacious for such purposes.

On December 6, 1940, no claimant having appeared, judgments of condemnation were entered and the products were ordered destroyed.

Nos. 336 to 339 report the seizure and disposition of intra-cervical or intra-uterine types of metal or rubber-covered stem pessaries which were potentially dangerous.

**336. Misbranding of pessaries. U. S. v. 2 Small and 6 Medium-Sized Pessaries (and 1 other seizure action against pessaries). Default decrees of condemnation and destruction.** (F. D. C. Nos. 2542, 2646. Sample Nos. 8936-E, 27361-E, 27362-E, 27363-E.)

On August 15 and October 1, 1940, the United States attorneys for the Northern District of Ohio and the District of Minnesota filed libels (the former amended on or about September 25, 1940) against 2 small and 6 medium-sized pessaries at Toledo, Ohio; and 5 small, 7 medium-sized, and 9 large pessaries at Minne-

apolis, Minn., alleging that the article had been shipped in interstate commerce within the period from on or about February 15 to on or about July 29, 1940, by H. Carstens Manufacturing Co. from Chicago, Ill.; and charging that it was misbranded in that it was dangerous to health when used with the frequency or duration prescribed. The article was labeled in part "X. L. Gold Pessary."

On November 15, 1940, and February 10, 1941, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

**337. Misbranding of pessaries. U. S. v. 18 Small and 47 Medium-Sized Pessaries. Default decree of condemnation and destruction.** (F. D. C. No. 2671. Sample Nos. 15870-E to 15873-E, incl.)

On August 23, 1940, the United States attorney for the Eastern District of Missouri filed a libel against 18 small and 47 medium-sized pessaries at St. Louis, Mo., alleging that the article had been shipped in interstate commerce within the period from on or about April 11 to on or about August 1, 1940, by the Gomco Surgical Manufacturing Corporation from Buffalo, N. Y.; and charging that it was misbranded in that it was dangerous to health when used with the frequency or duration prescribed. The article was labeled in part: "Gomco Perfect Pessary \* \* \* Small [or "Medium"] Size."

On September 21, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

**338. Misbranding of pessaries. U. S. v. 1 Large, 10 Regular, and 4 Small-Sized Cone Pessaries (and 1 other seizure action against pessaries). Default decrees of condemnation and destruction.** (F. D. C. Nos. 2714, 2780. Sample Nos. 5331-E, 6708-E.)

On August 31 and September 10, 1940, the United States attorneys for the District of Utah and the Northern District of Ohio filed libels against 1 large, 10 regular, and 4 small pessaries at Salt Lake City, Utah; and 6 large, 23 regular, and 6 small pessaries at Cleveland, Ohio, alleging that the article had been shipped in interstate commerce on or about March 6 and August 19, 1940, by the Medex Supply Co. from Denver, Colo.; and charging that it was misbranded. The article was labeled in part: "Flexible Large Size [or "Regular" or "Small Size"] Kone Pessary."

The article was alleged to be misbranded in that it was dangerous to health when used with the frequency or duration prescribed, recommended, or suggested in the following statements in the labeling: "1—Immerse the Flexible Kone Pessary in alcohol or some other good germicidal solution and dry it. 2—Place small capsule over prongs after bringing them together. 3—Fold the soft rubber button (see fig. 4) and grasp with lock forceps. 4—With patient in a dorsal recumbent position, the speculum in place, start the pessary into the os uteri with a slight rotating or up and down motion. The pessary will find the entire length of the canal without the knowledge of the patient. 5—Hold the pessary in place for one or two minutes to allow the gelatine capsule to dissolve, thus liberating the prongs. 6—Carefully remove the speculum so as to avoid displacing the pessary. 7—In conditions where there is a marked flexion of the cervical canal, the insertion of the small end of a Sterling dilator or other suitable instrument is advised, in order to be certain that the canal is open." The lot seized at Cleveland, Ohio, was alleged to be misbranded further in that the statement "Scientific Safe" borne on the label, was false and misleading.

On October 12 and December 4, 1940, no claimant having appeared, judgments of condemnation were entered and the product was ordered destroyed.

**339. Misbranding of pessaries. U. S. v. 12 Pessaries. Default decree of condemnation and destruction.** (F. D. C. No. 2625. Sample Nos. 27373-E, 27374-E.)

On August 21, 1940, the United States attorney for the Northern District of Ohio filed a libel against 12 pessaries at Cleveland, Ohio, alleging that the article had been shipped in interstate commerce within the period from on or about June 10 to on or about July 3, 1940, by the Penn Surgical Manufacturing Co., Inc., from Philadelphia, Pa.; and charging that it was misbranded in that it was dangerous to health when used with the frequency or duration prescribed. The article was labeled in part: "Penn Plated #1 [or "#3," "#4," "#5," or "#6.]"

On September 23, 1940, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.